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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,662

11/24/2003

Hong-Mo Moon

038779/271509

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06/01/2006

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,662

Applicant(s)

MOON ET AL.

Examiner

Zachariah Lucas

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 13-15 and 19-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 13 and 19-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-5, 13-15, and 19-43 are pending in the application.
2. In the prior action, mailed on December 20, 2005, claims 1-5 and 9-43 were pending; with claims 1-5, 13, and 19-43 withdrawn from examination; and claims 9-12 and 14-18 under consideration and rejected. In the Response of April 20, 2006, the Applicant cancelled claims 9-12, and 16-18; and amended claims 14 and 15.
3. Currently, claims 14 and 15 are under consideration.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claims 9 and 16 were objected to because of the following informalities: the use of the term “or” with respect to amino acid positions 15 and 123 is redundant to, or conflicts with, the “one or both” describing the asparagine residues at these positions. In view of the cancellation of the claims, the objection is withdrawn.

Claim Rejections - 35 USC § 101 and 112

5. **(Prior Rejection- Withdrawn)** Claims 9-12 and 14-18 were rejected under 35 U.S.C. 112, second paragraph, as being because it was unclear what is encompassed by the term “pIL20-pre-s” vector. In view of the cancellation of the indicated claim language from the claims, the rejection is withdrawn.
6. **(Prior Rejection- Withdrawn)** Claim 12 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. In view of the cancellation of the claim, the rejection is withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Withdrawn)** Claims 9-12 and 14-18 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement with respect to the pIL20-pre-S vectors referred to in the claims. In view of the cancellation of reference to these vectors in the claims, the rejection is withdrawn.

9. **(Prior Rejection- Maintained)** Claims 14-18 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a yeast transformant comprising a pIL20-pre-S vector that secretes the mutant pre-S into culture medium wherein the vector comprises a pre-S sequence operably linked to a leader or signal sequence, does not reasonably provide enablement for methods wherein the vector does not comprise such a leader sequence. Claims 16-18 have been cancelled from the application. The rejection is therefore withdrawn from these claims. Claims 14 and 15 have been amended to delete reference to the use of the pIL20-pre-S vector, but remain silent as to the presence or absence of a leader sequence. It is noted that the sequence of the leader sequence used in the expression vectors disclosed in Figure 1 does not appear in the disclosed sequence (SEQ ID NO: 11) identified in the claims. As the Applicant provides no argument with respect to this rejection, the rejection is maintained against claims 14 and 15 for the reasons of record.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Withdrawn)** Claims 9, 11, 12 and 14-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (U.S. 4,816,564), in view of the teachings (a) of Kniskern et al. (U.S. 5,614,384), Essex (U.S. Patent 6103, 238), and O.Narhi et al. (Protein Engineering 14: 135-40) and (b) of either of Lee et al. (Biotechnol Prog 75: 884-90) or Jang et al. (WO 98/54339). Claims 9, 11, 12, and 16-18 have been cancelled. The rejection is therefore withdrawn from these claims. Claims 14 and 15 have been amended to remove reference to the pIL20-pre-S vector, and to include reference to the double mutant pre-S sequence of SEQ ID NO: 11. Because these references do not teach or suggest the mutant of SEQ ID NO: 11, the rejection is withdrawn.

12. **(Prior Rejection- Maintained)** Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis in view of (a) Kniskern, Essex, and O.Narhi and (b) Lee or Jang as applied to claims 9, 11, 12 and 14-18 above, and further in view of Takahashi et al. (Arch Virol 143: 2313-26). Claim 10 was directed to recombinant vectors for the expression of the pre-S protein in the absence of a leader sequence wherein the vector comprises the double mutant pre-

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S protein of SEQ ID NO: 11. Claim 10 has been cancelled from the application, but the limitations thereof have been incorporated into amended claims 14 and 15. The rejection is therefore withdrawn from cancelled claim 10, but is extended to amended claims 14 and 15.

The Applicant traverses the rejection on the basis that no reference teaches each of the claimed limitations, and that none of the references contains specific teachings that would induce those in the art to combine the teachings of the references. These arguments are not found persuasive.

Because the rejection is based on a combination of references, the fact that no one of them teaches each of the claim limitations is not found persuasive. See e.g., MPEP § 2145 IV. Further, the motivation for the combination of the references need not be found in the references themselves. See e.g., MPEP 2143.01 (indicating that motivation to combine may also be found in the nature of the problem to be solved and the knowledge of those in the art). Those in the art would have had motivation to combine the teachings of the various references for the reasons indicated in the actions of January 2005 (pages 3-6), December 2005 (pages 8-10 and 12). As indicated in these actions, the various teachings of the references relate to the production of proteins in yeast cells, and to the modification of such to avoid unwanted N-glycosylation. From the teachings as described previously, those in the art would have been motivated to combine the teachings of these references to achieve the presently claimed invention.

Thus, for the reasons above and for the reasons of record, the Applicant's arguments in traversal are not found persuasive. The rejection is therefore maintained.

It is noted that, because the claims no longer contain reference to the pIL20-pre-S, the teachings of the Lee and Jang references are therefore moot for the purposes of the rejection.

Double Patenting

13. **(Warning- Withdrawn)** Applicant is advised that should claim 14 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. In view of the cancellation of claim 16, the warning s withdrawn.

14. **(Warning- Withdrawn)** Applicant is advised that should claim 9, or in the alternative claim 18, be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. In view of the cancellation of claims 9, 12, and 18, the warning is withdrawn.

Conclusion

15. No claims are allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

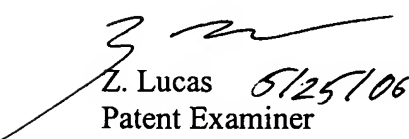
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

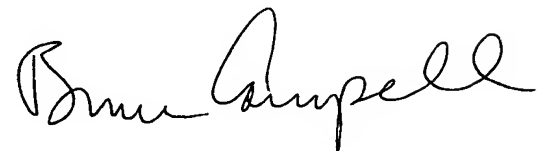
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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas 5/25/06
Patent Examiner



BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600